

REMARKS

In the present response, claims 1, 8 – 31 have been amended.

Specifically, all reference numerals have been deleted in the claims, claims 12, 14 – 21 have been deleted, previously deleted claims 25 – 31 have been resumed and the claim dependencies of claims 8, 9, 13, 22, 24, 28, 29 have been corrected.

Claim 1 has been amended by removal of the previously introduced features

- *"comprising a plurality of petals, wherein each petal comprises an arm which can broaden into a curved surface wherein the curved surface has an asymmetric conformation with respect to the respective arm, the petals"*
- *"and an intermediate position wherein the device is blocked from being moved to said open position until said handle is further manipulated, said means further comprising a continuous membrane for engaging dilating tissue in a continuous manner, the membrane being external to the petals when the petals are overlapping in the closed position,"*
- *"said means for locally dilating having a rounded non-traumatic tip."*.

Claim 1 has further been amended to state that

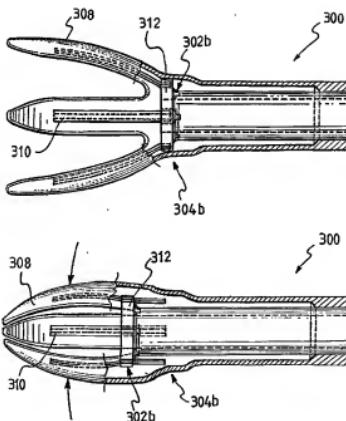
- *said elongated structure comprises an inner tube and an outer tube adapted to internally receive said inner tube,*
- *said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals,*
- *wherein said means for locally dilating comprise petals being arranged such that one first end thereof is associated to the distal end of the elongated tubular structure, said petals being adapted to assume at least one closed configuration and one open configuration,*
- *in which said petals are formed as one piece with said outer tube and each of said petals is coupled with a portion of said inner tube forming a unidirectional guide adapted to*

close or open the petals in response to the translation of the inner tube relative to the outer tube and the petals.

Support for the amendments can be found in original claims 1, 4, 12, 20 and 21. Accordingly, no new matter is involved.

ARGUMENTS

Due to the formation of the petals in one monolithic piece with the outer tube, the outer tube itself extends to form the petals, thereby providing a non-traumatic continuously smooth transition from the elongated structure (outer tube) to the petals. The claimed device further addresses the need of a simpler and more reliable construction of the diagnostic device and obviates hinges with pins between the petals and the elongated structure, which pin-hinges are difficult to assemble and may cause damage to the surrounding bodily tissue. Accordingly, the claimed invention combines non-invasiveness with a simplified and more reliable construction of the device (compare figs. 20, 21 and paragraph 156, last sentence).



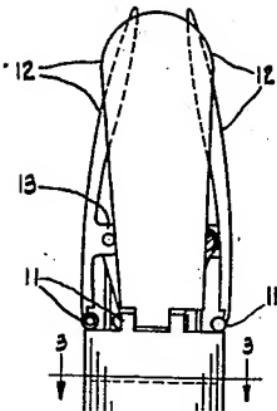
Detail of Figures 20 and 21 of application in re

In the previous office action the Examiner rejected Applicants' claim 1 under 35 USC 103 over Ewerhardt et al. in view of Pena. However, Ewerhardt and Pena fail to disclose a device in which

the petals are formed as one piece with the outer tube such that the outer tube itself extends to form the petals.

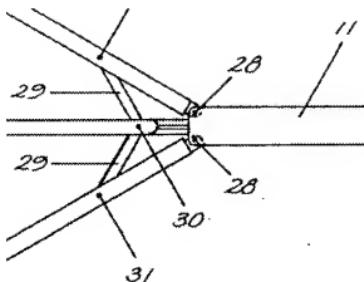
Ewerhardt (US 1,950,788) discloses (fig.1, page 1, lines 92 – 100) hinges 11 secured to the cylinder 10 ... One part of the hinges may be integral with the cylinder 10 and the other integral with the wing 12, when desired. However, Ewerhardt fails to disclose to form the petals as one piece with the outer tube.

Moreover, Ewerhardt describes to provide the wings 12 in an electrically conductive material (page 2, line 117) to apply high frequency electric current to a mouth of a cervix. A formation of the wings 12 as a single piece with the cylinder 10 would conduct the electric current also to the entire vaginal tract causing pain and trauma. Also for this reason, Ewerhardt teaches the skilled person away from forming the petals as one piece with the outer tube.



Detail of Figure 1 of US 1,950,788 (Ewerhardt)

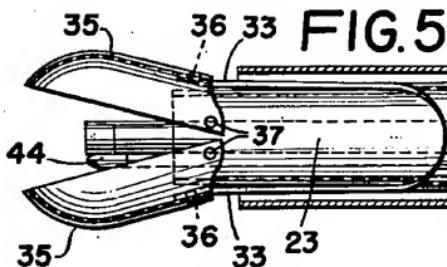
Pena (US 5,178,133) discloses that (figs.3,4, column 4, lines 3 to 7) operating arms 12 at said one end of support tube 11 are pivotally supported thereon by pivot pins 28. However, Pena fails to disclose to form the petals as one piece with the outer tube.



Detail of Figure 4 of US 5,178,133 (Pena)

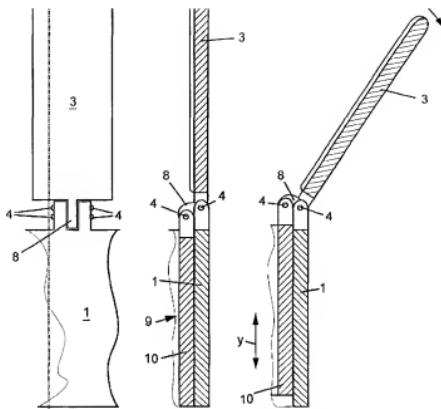
Also the remaining reference art fails to disclose or suggest to form the petals as one piece with the outer tube.

Wallace (US 2,621,651) discloses an instrument for dilating and examining the esophagus in which (col. 3, lines 45-48, col. 4, lines 36-40) each dilator member 35 is connected to a free end of a corresponding flexible arm 33, 133 by a rivet 36 and is pivoted to an inner tube by pins 37, 137. However, also Wallace fails to disclose to form the petals as one piece with the outer tube.



Detail of Figure 5 of US 2,621,651 (Wallace)

Sijp (DE19828099) discloses a rectoscope in which hinges 4 connect lamellae 3 to a connecting element 8 and the connecting element 8 movably connects the bushing 1 with the pushing element 9 (col. 3, lines 12 - 15. However, also Sijp fails to disclose to form the petals as one piece with the outer tube.



Detail of Figure 5 of DE19828099 (Sijp)

Yoon (US5,556,376) discloses a multifunctional device with a collection system 62 (Figs. 6,7, col. 10, lines 29-31) in which a collection bag 72 is attached to an inner member 70 in various ways, such as adhesively or mechanically including the use of various bonds or seals. However, also Yoon fails to disclose to form dilating petals as one piece with the outer tube.

Therefore, it is respectfully requested that the Examiner withdraw the rejection to claim 1. In addition, because all other claims depend from claim 1, Applicants respectfully request that the Examiner withdraw the rejections to these claims as well.

Therefore, Applicants respectfully request that the Examiner re-examine and favorably reconsider Applicants' claims in the form of a Notice of Allowance.

Respectfully submitted,

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